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IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, Commissioner, Maine Department of Human Services, and G. STEVEN ROWE, Attorney General of Maine,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF OF THE INTERNATIONAL PATIENT ADVOCACY ASSOCIATION, NATIONAL ALLIANCE FOR THE MENTALLY ILL - MICHIGAN, AND CALVIN P. FUHRMANN, M.D. AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI CURIAE*

Amici Curiae International Patient Advocacy Association and National Alliance for the Mentally Ill-Michigan represent beneficiaries of various state Medicaid entitlement programs funded and operated under federal law requirements. *Amicus curiae* Calvin P. Fuhrmann, M.D. is a physician practicing in Maine who treats Medicaid beneficiaries. *Amici* have a strong interest in this Court reversing the judgment below and enjoining the Maine Rx program to safeguard the benefits accorded to Medicaid beneficiaries by federal law.[1]

In 1990 and 1993, Congress amended the Medicaid program to give states the benefit of a federally established "best price" for prescription drugs and to ensure *amici* beneficiaries (and those providing medical care to them), the same access to those drugs as non-Medicaid patients, subject only to narrow and carefully crafted exceptions. If Maine and other states are permitted to impose burdensome prior authorization requirements on "best price" prescription drugs because their manufacturers refuse to accede to state demands unrelated to Medicaid, Medicaid beneficiaries will suffer. This litigation, and the other litigation pending in state and federal trial and appellate courts throughout the United States, makes it all too evident that the Maine Rx program, and others of its ilk, will not produce manufacturer acquiescence, at least until prescription drug use by Medicaid beneficiaries is ratcheted down sufficiently to make payment of non-Medicaid demands less onerous to manufacturers than the

1. Pursuant to Sup. Ct. Rule 37, the written consents of the parties to the filing of this brief have been filed with the Clerk. Counsel for the parties did not author this brief, in whole or in part, and no one other than the *amici curiae*, their members, and counsel made a monetary contribution to the preparation of this brief.

loss of Medicaid sales. Thus, Medicaid beneficiaries, contrary to their health interests and the protections afforded them by federal law, will be made the lever through which states seek to achieve non-Medicaid ends.

Amicus International Patient Advocacy Association ("IPAA") is a United States-based non-profit organization dedicated to patient advocacy both domestically and abroad. Through a network of volunteers, IPAA provides extensive support and assistance to patients throughout the United States and in several other countries. IPAA focuses in particular on meeting the needs of those with chronic illnesses or rare genetic disorders. Individual patients receive various forms of assistance, including aid in obtaining medical information, as well as in securing treatment and insurance coverage, access to legal resources, and participation in forums attended by members of the medical community. IPAA also serves patients' interests on a broader scale by advocating vigorously for patients' rights before state legislatures and Congress. In furthering its goals, IPAA works closely with physicians, medical industry representatives, and legislators. Because of its strong interest in protecting Medicaid beneficiaries, and in other Medicaid-related issues, IPAA also recently appeared as an *amicus* in a pending case challenging a program in Michigan similar to Maine Rx.

Amicus National Alliance for the Mentally Ill-Michigan ("NAMI-Michigan") was founded by families of individuals suffering from severe mental illness. The families served by NAMI-Michigan include those of Michigan residents who are diagnosed with major mental illnesses, including schizophrenia, bipolar disorder, major depressive disorder, and schizoaffective disorder. These individuals typically are very fragile and in need of lifelong medical assistance. Many

rely on Medicaid to provide access to prescription drugs. Changes in their drug regimen for any reason other than medical necessity can have dire consequences for them. NAMI-Michigan recently was granted leave to appear as an intervenor in the case now pending in the U.S. District Court for the District of Columbia concerning the Michigan program.

Amicus Dr. Calvin P. Fuhrmann is the Medical Director of the Kennebunk Medical Center in Kennebunk, Maine. The Kennebunk Medical Center is a busy primary care facility, and its two doctors and one nurse practitioner serve a diverse community – from the poorest of the poor to members of the President's family. The center treats an average of 50 patients per day, a number of whom are Medicaid recipients. Dr. Fuhrmann has personally experienced the added red tape and difficulties that prior authorization requirements impose on his staff and his patients. Very often, Dr. Fuhrmann chooses to prescribe what otherwise would be his second-choice drug to avoid prior authorization difficulties for himself and his patients. Dr. Fuhrmann believes that his Medicaid patients should not be denied access to the best medications for them merely so that other patients, who can afford to purchase prescription drugs outright, can obtain a discount through Maine Rx.

The Medicaid beneficiaries represented and cared for by *amici* are among those Americans least able to cope with administrative complexity or to assert their rights against state-created obstacles. Maine's interests in exerting economic leverage against pharmaceutical companies and in reducing the cost of its Medicaid drug benefit may be served by denying these Medicaid beneficiaries access to drugs they need, but beneficiaries' congressionally protected interests are not. Maine Rx will strike these beneficiaries at the

pharmacy level, when pharmacists are forced to demand full payment for prescriptions rather than a nominal Medicaid co-pay. Many beneficiaries will simply abandon the pursuit of necessary medication and accept the adverse health consequences. *Amici* prevail upon this Court to uphold the letter and spirit of the Medicaid laws and avoid this unacceptable result.

FACTUAL AND LEGAL BACKGROUND

A. Relevant Medicaid Provisions

The principal objective of the Medicaid program is "to furnish . . . medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services. . . ." 42 U.S.C. § 1396. Although Medicaid is administered by the states, Congress has imposed strict requirements on states for the protection of Medicaid beneficiaries. Each state must prepare a "Medicaid State Plan" in accordance with the statutory requirements set out in 42 U.S.C. § 1396a. The Act mandates that each state plan "provide such *safeguards as may be necessary to assure that . . . care and services will be provided, in a manner consistent with* simplicity of administration and *the best interests of [Medicaid] recipients.*" 42 U.S.C. § 1396a(a)(19) (emphasis added).

In order to protect vulnerable beneficiaries, Congress has enacted detailed legislation concerning the prescription drug benefits that states make available through Medicaid.[2] Prior

2. The Social Security Act, which governs Medicaid, does not mandate provision of a prescription drug benefit through Medicaid. However, as discussed below, the Act does establish strict and detailed requirements if such a benefit is conferred.

to the passage of OBRA-90, Medicaid drug prices were established at the state level, and some states used price-based "formularies" — restricted lists of covered drugs — to contain prescription drug expenditures. Congress explicitly recognized that this practice constrained Medicaid recipients' ability to obtain access to the drugs their doctors believed would be most effective for them but also recognized the need to husband limited state resources. To further the dual aims of broadening patient access to prescription medications and containing costs, Congress in 1990 established the Federal Medicaid Rebate Program as part of the Omnibus Budget Reconciliation Act of 1990 ("OBRA-90").[3] OBRA-90 abolished state formularies that excluded drugs from coverage for economic reasons and created a federal rebate program giving all state Medicaid programs the advantage of "best price" purchasing. This program entitled Medicaid beneficiaries to access all prescription drugs whose manufacturers agreed to provide federal "best price" rebates.[4] As stated in the related House Report,

> [b]ecause the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require States that elect to offer prescription drugs

3. 42 U.S.C. § 1396a(a)(54), *added by* Pub. L. No. 101-508, § 4401(a)(2)(C), 104 Stat. 1388 (1990); *see also* H.R. Rep. No. 101-881, at 96-97 (1990) ("OBRA-90 House Report"), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108-09 (describing preexisting law).

4. 42 U.S.C. § 1396b(i)(10), *added by* Pub. L. No. 101-508, § 4401(a)(1)(B), 104 Stat. 1388 (1990); *see also* OBRA-90 House Report, at 98, *reprinted in* 1990 U.S.C.C.A.N. at 2110.

> to cover all of the products of any manufacturer that agrees to provide price rebates.

H.R. Rep. No. 101-881, at 96-97 (1990) ("OBRA-90 House Report"), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108-09.

While OBRA-90 forbade states from excluding coverage of drugs for which manufacturers provided "best price" rebates, it did not leave states powerless to avoid needless or wasteful expenditures. Congress explicitly permitted states to impose limitations "on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste." 42 U.S.C. § 1396r-8(d)(6). Congress also allowed states to "subject to prior authorization any covered outpatient drug" so long as that categorization was consistent with the need for "efficiency, economy and quality of care." 42 U.S.C. § 1396r-8(d)(1)(A).[5] Prior authorization programs also were required to respond to authorization requests within 24 hours and to provide at least a 72-hour supply of the drug in an emergency without prior approval. 42 U.S.C. § 1396r-8(d)(5).

In 1993, Congress once again adjusted the "delicate balance between cutting program costs, improving the access of Medicaid patients to needed medicines, and preserving the incentives necessary to encourage continued pharmaceutical research and development." 136 Cong. Rec. 51579-02, 515859 (daily ed. Oct. 18, 1990), 1990 WL 158480 (statement of Sen. Hatch). In the Omnibus Budget Reconciliation Act of 1993 ("OBRA-93"), Pub. L. No. 103-

5. *See* OBRA-90 House Report at 98, *reprinted in* 1990 U.S.C.C.A.N. at 2110 (primary purpose of prior authorization is to assure that Medicaid payments for prescription drugs are "consistent with efficiency, economy and quality of care").

66, 107 Stat. 312, 616-17 (1993), Congress restored the authority of states to develop comprehensive formularies of preferred drugs but sharply limited their ability to exclude from those formularies the drugs of manufacturers that had entered into federal rebate agreements. Such drugs could be restricted on states' formularies

> only if . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

42 U.S.C. § 1396r-8(d)(4)(C).[6]

OBRA-93, which remains in effect, also redefined the concept of formulary for Medicaid purposes by eliminating exclusions from Medicaid coverage. Congress specifically required that every drug excluded from a (d)(4) formulary be available through a Medicaid-compliant prior authorization program. 42 U.S.C. § 1396r-8(d)(4)(D). Thus, Congress in OBRA-93 reaffirmed the basic commitment, first made in OBRA-90, that Medicaid beneficiaries would not be denied access to "best price" prescription drugs for non-clinical reasons.

As presently delineated in the Social Security Act ("the Act"), there are only three categories of drugs excluded from the requirement that Medicaid beneficiaries have access to all drugs manufactured by companies that have signed rebate

6. As a further protection, "Manufacturers could obtain judicial review of a decision to exclude a drug from a formulary." H.R. Rep. No. 103-111, at 205 (1993) ("OBRA-93 House Report"), *reprinted in* 1993 U.S.C.C.A.N. 378, 532.

agreements. *See* 42 U.S.C. § 1396r-8(d) (listing "[l]imitations on coverage of drugs"). First, states may "exclude or otherwise restrict coverage" of any drug when "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i).[7] Second, states may exclude certain categories of drugs that treat conditions deemed not sufficiently weighty to warrant Medicaid coverage, as well as drugs "subject to clinical abuse or inappropriate use." *See* 42 U.S.C. § 1396r-8(d)(2)-(3). Thus, for example, Congress did not require states to cover drugs intended to treat hair loss or provide symptomatic relief of coughs and colds, nor are the states required to cover barbituates. *See* 42 U.S.C. § 1396r-8(d)(2).

The third (and final) category through which states may restrict coverage of prescription drugs is through a formulary conforming to Section 1396r-8(d)(4). The formulary provision, unlike the more particularized exclusions in subsections (d)(1)(B) and (d)(2), contemplates systemic review of covered prescription drugs. However, the formulary provision added by OBRA-93 did not return to the pre-OBRA-90 exercise of discretionary, cost-based exclusion. Instead, Congress established a number of strict limits on states' abilities to create formularies. First, the formulary must be developed by a committee of physicians, pharmacists, or other qualified individuals (Subsection (d)(4)(A)). Second, the formulary must include all of a manufacturer's drugs if that manufacturer has agreed to provide a rebate (subsection (d)(4)(B)). States may only exclude a participating manufacturer's drug "with respect to the treatment of a specific disease or condition for an identified population" and only if they determine that it "does not have a significant, clinically meaningful therapeutic advantage" over other drugs included in the formulary. Even then, the decision

7. 42 U.S.C. § 1396r-8(d)(1)(B) also includes cross-references to subsections (d)(2) and (d)(4), which are discussed below.

must be supported by a "written explanation (available to the public) of the basis for the exclusion" (subsection (d)(4)(C)). Emphasizing the seriousness of dropping a drug into prior authorization by exclusion, this latter requirement was designed to permit judicial review. *See* H.R. Rep. No. 103-111, at 205 (1993) ("OBRA-93 House Report"), *reprinted in* 1993 U.S.C.C.A.N. 378, 532 ("[m]anufacturers could obtain judicial review of a decision to exclude a drug from a formulary").

The totality of the regime established by OBRA-90 and OBRA-93 thus establishes Congress' intent to protect beneficiaries' access to needed prescription drugs so long as the manufacturers of those drugs accept the federal rebate program.

B. The Maine Rx Program

Contrary to the requirements of the OBRAs, the Maine Rx program is intended to limit Medicaid beneficiaries' access to prescription drugs manufactured by companies that have agreed to provide federally-mandated rebates. Under Maine Rx, manufacturers whose drugs are sold in Maine are required to enter a separate rebate agreement with the state covering all drugs sold to participating Maine residents outside the Medicaid program. Me. Rev. Stat. Ann. tit. 22, § 2681(3) (West 2001). Participation in Maine Rx is open to all state residents; the rebate obligation (which is paid to the state, as in Medicaid) is triggered by a sale to any program enrollee. *Id.* Although the amount of the rebate theoretically is subject to negotiation, the Commissioner is instructed to use his "best efforts" to obtain the same rebate as provided for Medicaid sales. *Id.* § 2681(4)(C). If a manufacturer refuses

to pay the demanded rebate, its products are put into prior authorization status under Maine's Medicaid program, thereby pressuring the manufacturer to comply by sharply limiting beneficiaries' access to needed prescription drugs. *Id.* § 2681(7).

C. Impact of Maine Rx and Similar Programs on Beneficiaries and Providers

With Maine Rx in place, a Medicaid beneficiary could obtain a prescription for a medication she has been taking for years, including a prescription necessary to treat a serious or debilitating disease, only to have that prescription rejected for Medicaid reimbursement at the pharmacy. In this situation, the recipient's only recourse would be to (1) have her doctor prescribe a second-choice drug, if the doctor could be reached and any such drug were available, (2) have the doctor seek prior authorization (if the doctor were reachable and willing to invest the time necessary to do so), (3) pay for the entire prescription out-of-pocket herself, rather than the statutorily required "nominal" Medicaid co-payment,[8] or (4) forego altogether the prescribed drug or any substitute. A mix of these outcomes is likely and the magnitude of harm to Medicaid beneficiaries may vary in each individual situation from a minor inconvenience to a potential health emergency. In no case, however, is there any corresponding benefit to Medicaid beneficiaries. Moreover, the benefits sought by Maine lie entirely outside the Medicaid program.

If experiences in other jurisdictions are any guide, the scenarios outlined above will be widespread as soon as Maine Rx goes into effect. In Michigan, for example, the state recently implemented a non-Medicaid rebate agreement

8. 42 U.S.C. § 1396o(b)(3).

using the threat of Medicaid prior authorization as leverage. Most manufacturers refused to comply, thereby converting to prior authorization status hundreds of prescription drugs that had been readily available to Medicaid patients. *See Pharmaceutical Research & Manufacturers of America v. Thompson*, No. 02-CV-1306 (JDB) (D.D.C. filed June 28, 2002) (challenging federal approval of the Michigan Pharmaceutical Best Practices Initiative). No different outcome can be anticipated in Maine, particularly in view of the unrestricted nature of the Maine Rx program. Thus, Maine Rx will inflict immediate and potentially irreparable medical harm on Medicaid beneficiaries in Maine. Numerous other states already are enacting similar plans. Thus, if this Court does not reverse the decision below, similar harm soon will be visited upon Medicaid beneficiaries nationwide.

It is no answer to point to the possibility of obtaining prior authorization. Because of the numerous and varying lists of approved drugs (insurance companies, HMOs, Maine Rx, etc.), physicians cannot be expected to know, and often do not know, what drugs are approved without prior authorization for any given patient. The reality, therefore, is that numerous prescriptions for Medicaid beneficiaries will be written for drugs that are subject to prior authorization. This will be discovered by the beneficiary only when she arrives at the pharmacy to have her prescription filled. While this scenario is problematic for anyone, it is particularly problematic for indigent and/or disabled Medicaid beneficiaries, many of whom lack the capability and resources to pursue authorization diligently and overcome the inevitable (and intended) roadblocks. Moreover, Maine has every intention of declining prior authorization even when it is requested. As the First Circuit noted, "[t]he state concedes that it will not authorize payment for the first-choice drug

manufactured by a non-participant where there is another drug for the ailment manufactured by a participant." *Pharmaceutical Research & Mfrs. of America v. Concannon*, 249 F.3d 66, 77 (1st Cir. 2001). Indeed, Maine Rx's leveraging depends for its success on diminution of sales by manufacturers that decline to enter Maine Rx agreements.

Physicians who care for Medicaid beneficiaries, like *amicus* Dr. Fuhrmann, also will be harmed if Maine Rx is permitted to take effect. His patients, for whose care he is responsible, may be denied access to the prescription drugs that Dr. Fuhrmann determines in his professional judgment are best suited for them. Dr. Fuhrmann also will be compelled to divert attention from patient care in order to attempt to secure prior authorization. In the alternative, he can prescribe what could otherwise be a second-choice medication. Significantly, these would not be generic equivalents (determined to be pharmaceutically equivalent by FDA), but different chemical compounds altogether, which may have different dosing regimens, contraindications, and side effects. Thus, Dr. Fuhrmann's ability to treat his patients as effectively will be compromised if Maine Rx takes effect.

SUMMARY OF ARGUMENT

This case presents a question that is now of national import to Medicaid beneficiaries: whether federal law permits states to restrict the access of Medicaid beneficiaries to needed, "best priced" prescription drugs in order to serve non-Medicaid budgetary interests. Continuing judicial validation of the Maine scheme at issue would upset a carefully balanced structure established by Congress in 1990 and 1993, when it required (except in narrowly defined circumstances not applicable here) that the drug benefit in

state Medicaid programs provide beneficiaries access to all prescription drugs manufactured by companies that agree to pay rebates established by act of Congress.

Further, because Medicaid beneficiaries' access to necessary prescription drugs is being restricted in order to achieve non-Medicaid goals, the Maine Rx program is directly contrary to the "best interests" of Medicaid recipients and is therefore unlawful under the Social Security Act. Maine and the many other states poised to follow it should not be permitted to use the "prior authorization" provisions of the Act — which were intended to serve Medicaid purposes and apply only in limited circumstances — to pursue non-Medicaid state goals by putting at risk the ability of Medicaid beneficiaries to obtain the drugs that their physicians believe are best for them. Thus, the decision of the court of appeals should be set aside and the preliminary injunction entered by the district court reinstated.

ARGUMENT

I. MAINE RX CREATES AN UNLAWFUL DE FACTO MEDICAID FORMULARY THAT RESTRICTS MEDICAID BENEFICIARIES' ACCESS TO COVERED OUTPATIENT DRUGS CONTRARY TO STATUTORY REQUIREMENTS.

The Supremacy Clause, U.S. Const. art. VI, cl. 2, invalidates state laws that "interfere with, or are contrary to," federal law. *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824). "Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law." *Hillsborough County, Fla. v. Automated Med. Labs.*,

Inc., 471 U.S. 707, 713 (1985). Here, Maine Rx violates the protections established in the Act for Medicaid beneficiaries and is therefore unlawful.

As set out above, a core principle of the Act, post-OBRA-90 and OBRA-93, insofar as it pertains to prescription drugs, is that Medicaid beneficiaries will have unfettered access to all drugs whose manufacturers have agreed to pay the federally established Medicaid rebate. As stated in the House Committee report accompanying OBRA-90: "States that elect to offer prescription drug coverage under their Medicaid programs *would be required to cover all of the drugs of any manufacturers entering into and complying with such an agreement with the Secretary*." OBRA-90 House Report, at 98, *reprinted in* 1990 U.S.C.C.A.N. at 2110 (emphasis added). This trade-off — rebates for full and freely available coverage — is reflected in the statute. Consistent with prior practice, the new provisions included language directed at preventing waste, fraud, and abuse (*e.g.*, 42 U.S.C. § 1396r-8(d)(6), limiting quantities and refills), and reflected the judgment that certain conditions (*e.g.*, baldness, per *id.* (d)(2)(C)) were not worthy of coverage, but did not permit states on a more global basis to decline to cover drugs whose manufacturers had entered federal rebate agreements.[9]

OBRA-93 altered OBRA-90 to some degree, but not in a way that would save Maine Rx. OBRA-93 resurrected state formularies, which placed certain "best price" drugs in prior authorization status for clinical reasons subject to strict requirements for Medicaid beneficiary protection that Maine Rx does not meet. Subsection (d)(4)(C) provides:

9. The prior authorization provision in 42 U.S.C. § 1396r-8(d)(1)(A) relied upon by the First Circuit does not affect this conclusion, for the reasons discussed in Part II, *infra*.

> A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

42 U.S.C. § 1396r-8(d)(4)(C). The Maine Rx program has no such clinical component, however, let alone an exclusive focus on clinical factors. *See* Me. Rev. Stat. Ann. tit. 22, § 2681 (West 2001). Rather, its exclusion criterion is a *non-Medicaid economic factor*, namely failure to acquiesce to the non-Medicaid rebate demanded by the state. This linkage is unlawful even in the view of courts that have taken a broad view of prior authorization authority. As the Eleventh Circuit recently concluded, exclusion from a (d)(4) formulary "must be based solely on clinical factors." *Pharmaceutical Research & Mfrs. of America v. Meadows*, No. 02-10151, 2002 WL 31000006, at *9 (11th Cir. Sept. 6, 2002).[10]

While Maine has claimed that it will establish a committee to review exclusion determinations, the unmistakable import of the Maine Rx statute is that drugs are to be placed in prior authorization status (*i.e.*, excluded

10. In the view of the undersigned *amici*, the Eleventh Circuit erred by, among other things, reading the prior authorization provision in 42 U.S.C. § 1396r-8(d)(1)(A) so broadly as to eviscerate the formulary provision of 42 U.S.C. § 1396r-8(d)(4). The case is discussed in Part II, *infra*.

from the formulary) based on a single economic factor — the presence or absence of a non-Medicaid rebate agreement — rather than the precise, detailed therapeutic factors that Congress has required in subsection (d)(4)(C). *See* 42 U.S.C. § 1396r-8(d)(4)(C). In addition, Maine Rx makes no provision for the public, judicially reviewable exclusion findings that Congress contemplated. *See* OBRA-93 House Report, at 205, *reprinted in* 1993 U.S.C.C.A.N. at 532. Maine Rx contemplates an essentially binary, unreviewable decision as to whether the manufacturer has acceded to the non-Medicaid rebate demanded by the state in order to develop a comprehensive list of automatically approved and prior authorization drugs. As such, Maine Rx constitutes an unlawful, *de facto* formulary that violates the requirements of the Act.[11]

II. PRIOR AUTHORIZATION AUTHORITY UNDER MEDICAID CANNOT BE CONSTRUED TO EVISCERATE THE FUNDAMENTAL BALANCE OF THE ACT, INCLUDING THE PROTECTION OF BENEFICIARY ACCESS TO PRESCRIPTION DRUGS.

Maine has defended the Maine Rx program on the ground, accepted by the First Circuit, that essentially anything goes when it comes to Medicaid prior authorization

11. Maine has acted unilaterally against the interest of Medicaid recipients, without even officially altering its Medicaid state plan or obtaining the requisite federal approval. *See* 42 C.F.R. § 430.12(c)(ii) (State plan amendment must be submitted "whenever necessary to reflect . . . [m]aterial changes in State law, organization, or policy, or in the State's operation of the Medicaid program"). Forcing most prescription drugs into prior authorization status surely qualifies as a "material change[ ] . . . in the State's operation of the Medicaid program." *Id.*

requirements. In substance, Maine contends, taking the language of 42 U.S.C. § 1396r-8(d)(1) in isolation, that it can impose any prior authorization requirements that it wishes, for any reasons that it wishes, so long as it complies with the 24-hour response/72-hour emergency supply provision in 42 U.S.C. § 1396r-8(d)(5). The First Circuit agreed. *See PhRMA v. Concannon*, 249 F.3d at 76-77.

Maine's reading cannot be reconciled with the overall structure of the Act or its intended purpose. Acceptance of Maine's position would both upset the overall balance created by Congress in OBRA-90 and OBRA-93 and vitiate the detailed formulary provisions added in OBRA-93. Such an outcome cannot withstand scrutiny. *Reves v. Ernst & Young*, 494 U.S. 56, 63 (1990) ("the phrase 'any note' should not be interpreted to mean literally 'any note,' but must be understood against the backdrop of *what Congress was attempting to accomplish*" (emphasis added)). "Statutory construction . . . is a holistic endeavor." *United Savings Ass'n v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988). Broad statutory provisions must be read in context, because often "only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law." *Id.* (citations omitted).

As discussed above, the fundamental bargain reflected in the OBRAs was full beneficiary access in return for manufacturer rebates. *See* OBRA-90 House Report, at 95-98, *reprinted in* 1990 U.S.C.C.A.N. at 2107-10. Prior authorization, which originally was intended to prevent waste, fraud, and abuse in particularized circumstances, was not intended to give the states authority to develop a comprehensive, back-door formulary which would circumvent this balance carefully set by Congress:

As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care. However, the *Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements — i.e., assuring access by Medical beneficiaries to prescription drugs where medically necessary.*

OBRA-90 House Report, at 98, *reprinted in* 1990 U.S.C.C.A.N. at 2110 (emphasis added).

The detailed formulary provisions added by Congress in OBRA-93 confirm this view. Under the OBRA-93 provision, formularies cannot totally exclude drugs whose manufacturers have signed national "best price" agreements, unless these drugs are not of a type otherwise subject to exclusion under (d)(1)(B) or (d)(2). Rather, "exclusion" of a drug from a formulary is limited to placing that drug in prior authorization status. *See* 42 U.S.C. § 1396r-8(d)(4)(D) (one formulary requirement is that "[t]he state plan permits coverage of a drug excluded from the formulary . . . pursuant to a prior authorization program").[12]

12. The Eleventh Circuit, in dealing with a Florida program that did not include non-Medicaid rebate criteria, read the 42 U.S.C. § 1396r-8(d)(4) formulary provision as permitting complete exclusion (Cont'd)

If Maine's view were correct — that subsection (d)(1)(A) provided an unlimited right to impose prior authorization — the subsequently enacted formulary provision in subsection (d)(4) would be meaningless, because no state would ever comply with its strictures (plus subject formulary decisions to judicial review) when exactly the same result could be reached under the pre-existing subsection (d)(1) without the need for a committee, without the need for a substantive standard, without the need for a reasoned decision, and without the possibility of judicial review. It is well-established that statutes should not be interpreted so as to render parts of them meaningless. *Astoria Fed. Savings & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991) (courts should construe statutes "to avoid rendering superfluous any parts thereof"); *United States v. Menasche*, 348 U.S. 528, 538-539, (1955) (court has a "duty to give effect, if possible, to every clause and word of a statute" (quoting *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883)). That is exactly the result that would obtain were the Court to accept Maine's

(Cont'd)
of coverage of a drug, as opposed to a mere prior authorization requirement. *See Meadows*, 2002 WL 31000006, at *9. In fact, however, Congress unequivocally precluded full exclusion through a (d)(4) formulary. *See* 42 U.S.C. § 1396r-8(d)(4)(D) (state plan must "permit [] coverage of a drug excluded from the formulary . . . pursuant to a prior authorization program"). The Eleventh Circuit also relied on a finding that "approval of the prescribing doctor's first-choice drug is guaranteed in 100 percent of all cases, provided only that he or she make the telephone call." *Meadows*, 2002 WL 31000006, at *1. No such guarantee protects Medicaid beneficiaries threatened by Maine Rx. To the contrary, as the First Circuit noted, Maine "concedes that it will not authorize payment for the first-choice drug manufactured by a non-participant where there is another drug for the ailment manufactured by a participant." *Pharmaceutical Research & Mfrs. of America v. Concannon*, 249 F.3d 66, 77 (1st Cir. 2001).

reading of subsection (d)(1)(A). *United States v. Fausto*, 484 U.S. 439, 453 (1988) (the "classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute").

The error in the First Circuit's analysis is revealed by its Opinion. The First Circuit failed to consider the overall legislative structure and history and, in particular, failed to consider how its broad (indeed, essentially unlimited) view of the prior authorization provision in subsection (d)(1)(A) could be reconciled with the other provisions (particularly the (d)(4) formulary provision) of the statute with which it was intended to work in concert. *See PhRMA v. Concannon*, 249 F.3d at 76-78. This consideration of one provision in isolation was error. *See, e.g., John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank*, 510 U.S. 86, 94-95 (1993) (in interpreting a complex statute, Court must look at "the language of the governing statute, guided not by a single sentence or member of a sentence, but look[ing] to the provisions of the whole law, and to its object and policy" (internal quotations and citations omitted)); *Brown v. Duchesne*, 60 U.S. (19 How.) 183, 194 (1856) ("And it is well settled that, in interpreting a statute, the court will not look merely to a particular clause in which general words may be used, but will take in connection with it the whole statute . . . and the objects and policy of the law. . . ."). Because the construction adopted by the First Circuit would overturn the balance established by Congress between ensuring access to drugs and cost savings, it cannot be accepted by this Court.

III. PRIOR AUTHORIZATION AS IMPLEMENTED IN MAINE RX ALSO IS UNLAWFUL BECAUSE IT IS DIRECTLY ADVERSE TO — RATHER THAN IN THE "BEST INTERESTS OF" — MEDICAID BENEFICIARIES.

There can be no dispute that Maine Rx does not serve — and, in fact, actually disserves — the interests of Medicaid beneficiaries in Maine. The program expressly contemplates restricting access of Medicaid beneficiaries to necessary prescription drugs (through prior authorization) in order to secure rebates for a non-Medicaid (and not universally needy) population. Even if prior authorization were otherwise freely available under the Act, which the foregoing analysis shows that it is not, this anti-beneficiary purpose is contrary to the Act and must not be sustained.

Congress requires states to provide covered Medicaid services in a manner consistent with "the *best interests* of [Medicaid] *recipients*." 42 U.S.C. § 1396a(a)(19) (emphasis added). The Social Security Act requires a focus on *recipients*' best interests, not those of the states' population as a whole. Individual Medicaid recipients are not well-served by restricting their access to prescription drugs. Whatever authority states have to "subject to prior authorization any outpatient drug," 42 U.S.C. § 1396r-8(d)(1)(A), this grant cannot be read untethered from the moorings of the remaining provisions of Section 1396r-8. *United States v. Sun-Diamond Growers of Calif.*, 526 U.S. 398, 406 (1999) (holding that "the more natural meaning, especially given the complex structure of the provision," of a phrase including the term "any" was that "any" referred to "for or because of some particular" rather than "all").

The First Circuit recognized that Maine Rx uses Medicaid tools outside the strictures of a federally approved Medicaid State plan, but held that Maine Rx was nonetheless an acceptable use of the Medicaid program. The First Circuit's conclusory assertion that the absence of a Medicaid purpose "does not mean that the prior authorization scheme *conflicts* with the objectives of the Medicaid program" cannot be countenanced. *PhRMA v. Concannon*, 249 F.3d at 76. Indeed, that conclusion flies in the face of the fact that Maine Rx will restrict beneficiary access to prescription drugs, contrary to Congress' commitment to beneficiaries in 42 U.S.C. § 1396a(a)(19) and in the OBRAs. "[T]his theory . . . is implausible even in the abstract, but even more so in light of the historical principles" of the statute in question. *United Savings Ass'n of Texas v. Timbers*, 484 U.S. at 373. Likewise, the First Circuit's conclusion that prior authorization can be used for any purpose whatsoever[13] simply cannot be squared with the best interests provision of the Act and the carefully structured limitations of (d)(2) and (d)(3). *See* 42 U.S.C. §§ 1396a(a)(19), 1396r-8(d)(2), (d)(3).

13. *PhRMA v. Concannon*, 249 F.3d at 76 ("we are not convinced that the Medicaid statute is concerned with the motivation behind imposing prior authorization, so long as the [24/72] requirements are satisfied").

CONCLUSION

The Medicaid statute contemplates that states will use prior authorization to restrict patients' access to certain prescription drugs only in very specific circumstances — in combination with a carefully crafted formulary, or to control fraud and abuse, but always in keeping with the overarching goal of providing for the best interests of Medicaid recipients. *Any* use of prior authorization unhooked from Medicaid's purposes for such an added administrative burden *necessarily* conflicts with the objectives of Medicaid.

As the Solicitor General recognized, "Congress assuredly did not intend that a State would use a requirement of prior authorization for the prescription of drugs for Medicaid beneficiaries in a manner that would burden the ability of Medicaid recipients to receive covered drugs without serving *some* purpose related to Medicaid." U.S. Br. at 14 (emphasis added). Further, the Solicitor General explicitly recognized that "no Medicaid purpose appears to be served" by the Maine Rx program. U.S. Br. at 16. In these circumstances, the program cannot be sustained and the decision below must be reversed.

Respectfully submitted,

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